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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

Plaintiff,

v.

BAYER CORPORATION,

Defendant.

Case No. 2:07-cv-00001 (JLL)(JAD)

GOVERNMENT'S PROPOSED
FINDINGS OF FACT AND
CONCLUSIONS OF LAW

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FINDINGS OF FACT 1

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

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CONCLUSIONS OF LAW.....71

Plaintiff United States of America submits the following proposed findings of fact and conclusions of law pertinent to the trial in this matter:

FINDINGS OF FACT

[REDACTED]

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Pages 2-70 are redacted.

CONCLUSIONS OF LAW

1. Courts possess inherent authority to enforce compliance with their orders through civil contempt. *Shillitani v. United States*, 384 U.S. 364, 370 (1966).

2. “[C]ivil contempt may be employed to coerce the defendant into compliance with the court’s order and to compensate for losses sustained by the disobedience.” *McDonald’s Corp. v. Victory Invs.*, 727 F.2d 82, 87 (3d Cir. 1984).

3. In order for a party to be held in contempt, the moving party must show “(1) that a valid order of the court existed; (2) that the defendant[] had knowledge of the order; and (3) that the defendant[] disobeyed the order.” *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575, 582 (3d Cir. 2010) (quoting *Marshak v. Treadwell*, 595 F.3d 478, 485 (3d Cir. 2009)). There is no dispute in this matter with respect to the first two requirements, as there is no question that the order entered by this Court on January 3, 2007, is a valid court order, Dkt. No. 2, [REDACTED]

[REDACTED]

4. The party seeking civil contempt must prove it by clear and convincing evidence, *Lane Labs-USA*, 624 F. 3d at 582, which is proof greater than a preponderance of the evidence but less than proof beyond a reasonable doubt, *Aranjo v. N.J. Transit Rail Operations, Inc.*, 708 F.3d 152, 159 (3d Cir. 2013); *see also Colorado v. New Mexico*, 467 U.S. 310, 316 (1984) (when “the truth of [the] factual contentions are ‘highly probable’”).

5. The issue before the Court is whether Bayer possessed and relied upon

“‘competent and reliable scientific evidence’ to substantiate any representation it makes ‘about the benefits, performance, efficacy, safety or side effects’ of any of its dietary supplements — when making specific claims about constipation, diarrhea, and gas and bloating in connection with its Phillips’ Colon Health product.” Dkt. No. 47, at 2 (order directing Bayer to show cause).

6. Black’s Law Dictionary defines “possess” as “[t]o have in one’s actual control; to have possession of.” *Possess, Black’s Law Dictionary* (10th ed. 2014).

7. Black’s Law Dictionary defines “maintain” as “[t]o continue in possession of (property, etc.).” *Maintain, Black’s Law Dictionary* (10th ed. 2014).

8. The 2007 Order requires Bayer to “*maintain* and, upon request, make available to the Commission, *copies of all business records demonstrating compliance* with the terms and provisions of this Consent Decree,” including “[a] copy of each advertisement containing any representation covered by this Consent Decree” and “[a]ll materials that were relied upon in disseminating such representation,” for five years from the date of the Order. Dkt. No. 2 § VI.C & D, at 6–7 (emphases added).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9. An advertisement’s meaning is a question of fact. *FTC v. Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff’d*, 356 F. App’x 358 (11th

Cir. 2009); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957–58 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008). “When assessing the meaning and representations conveyed by an advertisement, the court must look to the advertisement’s overall, net impression rather than the literal truth or falsity of the words in the advertisement.” *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1189; *cf. In re Nat’l Credit Mgmt. Grp., LLC*, 21 F. Supp. 2d 424, 441 (D.N.J. 1998) (“[A] court is not limited to express claims, but may also look to the overall net impression conveyed by the advertising and promotional statements of a defendant.”).

10. Where implied claims are conspicuous and “reasonably clear from the face of the advertisement[],” extrinsic evidence is not required to establish the existence of implied claims. *Kraft, Inc. v. FTC*, 970 F.2d 311, 320 (7th Cir. 1992); *cf. FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 386 (1965) (finding a certain claim “rest[ed] on an inference that could reasonably be drawn from the commercials themselves”).

11. Injunctions, including consent decrees, must comply with Federal Rule of Civil Procedure 65(d), which requires that an injunction “state its terms specifically” and “describe in *reasonable* detail . . . the act or acts restrained or required.” Fed. R. Civ. P. 65(d) (emphasis added). The 2007 Order’s prohibitions concerning unsubstantiated claims are specific and describe in reasonable detail what is required to substantiate dietary supplement efficacy claims by providing a clear definition of “competent and reliable scientific evidence.”

12. A party will not be held in contempt of a court order if that order is so

vague or indefinite that the party subject to the order lacked certainty as to what the order prohibited or directed. *Harris v. City of Philadelphia*, 47 F.3d 1342, 1349–50 (3d Cir. 1995). That is not the case here; the 2007 Order’s prohibitions concerning unsubstantiated claims, and its direction that Bayer must possess and rely upon “competent and reliable scientific evidence” as defined in the 2007 Order to substantiate any dietary supplement efficacy claim at the time it makes the claim, are clear and unambiguous.

13. It is well settled that what is deemed to be “competent and reliable scientific evidence” is context specific and depends on expert evaluation. *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1186; *see also QT*, 448 F. Supp. 2d at 961–62 (N.D. Ill. 2006) (finding an RCT necessary as competent and reliable scientific evidence for a specific claim based on expert testimony).

14. The Third Circuit also agrees that competent and reliable scientific evidence is claim-specific and involves expert testimony. *See Lane Labs-USA*, 624 F.3d at 583–87 (upholding a district court’s reliance on experts to find competent and reliable scientific evidence for some claims, yet reversing as clear error findings of no contempt where experts revealed a lack of substantiation).

15. If, as Bayer asserts, the specific way in which the competent and reliable standard applies to each claim must be explicitly written into the “four corners” of the 2007 Order, the underlying “competent and reliable scientific evidence” standard could never be sufficiently clear without delineating the specific scientific

substantiation necessary for every conceivable covered claim. In addition, the drafting of injunctions would become an uncertain exercise in prognostication as this Court could protect against future misconduct only if it successfully predicted every single type of claim that creative wrongdoers might use. That disruptive outcome is the direct implication of Bayer's "four corners" argument.

16. In *FTC v. Lane Labs-USA, Inc.*, the consent order at issue prohibited the defendants from making any express or implied health benefit claims about a dietary supplement unless they possessed and relied upon competent and reliable scientific evidence to substantiate the claim. 624 F.3d 575, 578 (3d Cir. 2010). The order's definition of "competent and reliable scientific evidence" was similar to that contained in the 2007 Order. *See id.* Based on expert testimony as to whether the claims were substantiated by competent and reliable scientific evidence, the Third Circuit upheld the District Court's reliance on experts to find that competent and reliable scientific evidence substantiated some claims. The Third Circuit continued to focus on the importance of expert opinion when it reversed as clear error findings of no contempt where expert testimony revealed a lack of substantiation. *Id.* at 583–87. Following the guidance of *Lane Labs*, this Court holds that the application of what is competent and reliable scientific evidence for the specific claims at issue in this case is a factual matter that must be determined on the basis of evidence.

17. In *FTC v. Nat'l Urological Grp., Inc.*, the defendants argued in a motion for summary judgment that FTC's requirement of "competent and reliable scientific

evidence” was impermissibly vague because it did not “provide sufficient certainty about the criteria the FTC uses to evaluate the scientific support for ingredient-specific claims”; did not “establish requirements for size, duration, or protocol of a scientific study”; did not “provide any single fixed formula for the number or type of scientific studies required to substantiate a claim”; and did not “specify the proper mechanism for extrapolating results of a study.” 645 F. Supp. 2d 1167, 1186 (N.D. Ga. 2008), *aff’d*, 356 F. App’x 358 (11th Cir. 2009). Referring to the 2001 FTC Guidance’s definition of “competent and reliable scientific evidence,” the District Court found “no reason why this definition would not give people of ordinary intelligence a reasonable opportunity to understand what evidence is required to substantiate their health-related claims” and that this “context specific” definition “permits different variations . . . depending on what pertinent professionals would require for the particular claim made.” *Id.* The court thus concluded that “the standard by which these issues of fact are resolved is clear, and an advertiser can be reasonably certain of what substantiation will be required by conferring with appropriate professionals or experts.” *Id.* at 1186–87. Ultimately, the court found that the defendants lacked competent and reliable scientific evidence for its claims based on the testimony of experts. *See id.* at 1202–03. Similarly, this Court finds that the 2007 Order’s definition of “competent and reliable scientific evidence” provides Bayer with a reasonable opportunity to determine what is necessary to substantiate *any* possible dietary supplement efficacy claim it may make — now, or in the future —

including those it makes for PCH.

18. Earlier this year, the D.C. Circuit Court performed a similar analysis in the *POM Wonderful* matter. After considering the specific claims that pomegranate-based products were efficacious for heart disease, prostate cancer, and erectile dysfunction, the court determined that the marketer had made misleading or false advertisements and that it was appropriate for FTC to prospectively require at least one RCT to substantiate claims concerning the treatment or prevention of disease. *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 483–44 (D.C. Cir. 2015). That case did not, however, address the level of substantiation necessary for other types of claims that were not at issue. *Id.* at 494. Nor does this Court need to address the level of substantiation necessary for other claims for other dietary supplements, because only Bayer’s specific claims about constipation, diarrhea, and gas and bloating for PCH’s three-strain formula are at issue in this case.

19. Notice-and-comment rulemaking is not a prerequisite for applying the standard of competent and reliable scientific evidence to Bayer’s specific efficacy claims for PCH. *POM Wonderful LLC*, 777 F.3d at 497.

20. In *FTC v. Garden of Life, Inc.*, the court considered expert evaluation to determine if the defendant possessed and relied upon competent and reliable scientific evidence to substantiate specific claims. 845 F. Supp. 2d 1328, 1334–35, 37 (S.D. Fla. 2012), *aff’d in relevant part*, 516 F. App’x 852 (11th Cir. 2013). [REDACTED]

[REDACTED] the *Garden of Life* court noted that after a stipulated injunction was in place, the

defendant relied on an outside expert's evaluation of certain claims *before* the defendant made the claims. *Id.* at 1330, 1334–35 (“[T]he evidence establishes that [the defendant] hired an outside expert to evaluate whether the aforementioned representations were supported by competent and reliable scientific evidence.”), 1337 (defendant relied on its expert's report). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

21. In a non-contempt case, the court in *Basic Research, LLC v. FTC* also made factual findings concerning what experts in the field expected as competent and reliable scientific evidence for the claims at issue. No. 09-0779, at 3–10 (D. Utah Nov. 25, 2014). [REDACTED] however, the *Basic Research* court further found that the defendant relied on outside experts' evaluation of a “double-blind, placebo controlled, peer-reviewed, published study” to support certain of its specific advertising claims, and that there was no dispute that this study was competent and reliable scientific evidence. *Id.* at 3, 5, 7. The court similarly found that the defendant relied on outside experts' evaluation of the scientific evidence to substantiate other claims *before* the defendant made such claims. *Id.* at 10–11. [REDACTED]

[REDACTED]

22. The *Basic Research* court's opinion is also based on its interpretation of the agreement at issue, which included language concerning the defendant's need to

“possess and rely upon a reasonable basis for the representation,” *id.* at 19–20 — language that is not present in the 2007 Order.

23. To the extent Bayer suggests that *Basic Research* stands for the proposition that Bayer cannot be held in contempt for its unsubstantiated PCH claims because the 2007 Order does not detail that Bayer’s claims that a daily dose of PCH is efficacious for constipation, diarrhea, and gas and bloating in healthy people must be substantiated with an RCT of the three-strain formula of PCH in a healthy population, this Court declines to adopt Bayer’s interpretation as it conflicts with case law in the Third Circuit as well as others recognizing that what is “competent and reliable scientific evidence” requires expert testimony and is context-specific. *See, e.g., POM Wonderful*, 777 F.3d at 493–95; *Lane Labs-USA*, 624 F.3d at 583–87; *Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d at 1186.

24. What doctors do in the practice of medicine is different from the requirement that Bayer, as the advertiser, possess appropriate substantiation for the representations of efficacy it chooses to make to consumers in an attempt to entice those consumers to purchase a particular product. *See In re Thompson Med. Co.*, 104 F.T.C. 648, 751 (1984) (Initial Decision) (“[T]he practice of medicine is not an exact science but an art and a physician’s choice of a drug for a particular patient essentially reflects a process of trial and error based on long experience, insight and wisdom. However, it is something else to argue that clinicians’ experience with patients with a particular drug should be accepted as scientific proof of efficacy.”), *aff’d*, 104 F.T.C at

839 (Opinion), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986).

25. The Dietary Supplement Health and Education Act of 1994 (“DSHEA”), Pub. L. No. 103-417, 108 Stat. 4325, 4329, § 6 (1994) provides an exception to the misbranding provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”) for certain health-related claims. *See as codified* 21 U.S.C. § 343(r)(6) (dietary supplements making claims meeting the exception will not be deemed to be misbranded food). Under the FDCA, introducing or delivering for introduction into interstate commerce a misbranded food is a prohibited act subject to criminal penalties. 21 U.S.C. §§ 331(a); 333(a).

26. In FDA’s Final Rule about whether a claim qualifies for DSHEA’s exception for misbranding, FDA made clear that “[t]he requirement that structure/function statements and other statements for dietary supplements . . . be adequately substantiated is distinct from the requirement that such statements not claim to diagnose, treat, mitigate, cure, or prevent disease. Both of these requirements are imposed by the statute and must be complied with.” *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 65 Fed. Reg. 1000, 1032 (Jan. 6, 2000). Accordingly, whether Bayer’s claims are structure-function claims or not is irrelevant in this matter, as its claims must be properly substantiated regardless.

27. In FDA’s Final Rule, FDA declined to provide “what types of evidence should constitute adequate substantiation” for structure-function claims, noting that

the Final Rule was not the “appropriate venue to address the substantiation requirement.” *Id.* Thus, the Final Rule has no application in this matter as it does not address substantiation for advertising claims.

28. Although companies must submit to FDA notices of certain dietary supplement claims made on its label or labeling no later than thirty days after first making the claims, companies do not have to submit notice to FDA of dietary supplement claims a company makes beyond the product’s label or labeling, like those made in commercials and print advertisements. *See* 21 C.F.R. § 101.93(a). When submitting notice to FDA of dietary supplement label or labeling claims, a company also is not required to submit its substantiation evidence for those claims. *See id.* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

29. The Supreme Court rejected the idea that compliance with the FDCA and FDA’s rules precluded the enforcement of a complementary federal consumer protection law. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. ___, 134 S. Ct. 2228, 2237–42 (2014) (holding that the FDCA did not preclude Lanham Act actions concerning food and beverage labels also regulated by the FDA).

30. DSHEA contains no provision precluding other federal consumer

protection laws, such as the Federal Trade Commission Act, which was the basis for the complaint that resulted in the 2007 Order. *See* 108 Stat. 4325; Dkt. No. 1 at 1. Bayer's compliance or non-compliance with DSHEA is therefore legally irrelevant to whether Bayer complied with the 2007 Order's prohibitions concerning unsubstantiated claims.

31. "A party substantially complies [with a court order] when it takes all reasonable steps to do so, but nonetheless contravenes the court order by good faith mistake or excusable oversight." *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575, 590 (3d Cir. 2010). To take advantage of the substantial compliance defense, "a party must show that it (1) has taken all reasonable steps to comply with the valid court order, and (2) has violated the order in a manner that is merely 'technical' or 'inadvertent.'" *Id.* at 591.

32. Substantial compliance is an affirmative defense. *See id.* at 590 n. 18. Accordingly, the burden is on Bayer to prove that their violations of the 2007 Consent Decree are technical or inadvertent. *See id.* at 591.

33. Courts have found that a violation of an injunction is neither technical nor inadvertent where the core conduct prohibitions of the order have been violated. *See, e.g., Pub. Interest Research Grp. v. Top Notch Metal Finishing Co.*, CIV. A. No. 87-3894, 1988 WL 156725, *1, *5 (D.N.J. Dec. 23, 1988) (where order prohibited wastewater discharge in violation of permitting standards, finding contempt in face of "numerous and serious" violations of conduct prohibition, even where contemnor later made

substantial efforts to comply with order); *Halderman v. Pennhurst State Sch. & Hosp.*, 154 F.R.D. 594, 608–09 (E.D. Pa. 1994) (finding there would be no substantial compliance even if contempt defendants had complied with key conduct prohibitions of order as to most class members, but not all); *Al-Adabi v. Obama*, 672 F. Supp. 2d 114, 117 (D.D.C. 2009) (finding that, where order required testimony of witness to be videotaped, failure to videotape testimony was not “inadvertent,” despite being the result of “oversight and miscommunication”); *On Command Video Corp. v. LodgeNet Entm’t Corp.*, 976 F. Supp. 917, 922–23 (N.D. Cal. 1997) (reversing magistrate judge’s finding of a “technical violation” where information obtained in discovery was used to file a separate lawsuit in violation of a protective order prohibiting use of confidential information, despite fact that contemnor took steps to prevent public disclosure of that information).

34. Courts have found three other circumstances where violations are neither technical nor inadvertent: (1) where the violator consciously chose to undertake the conduct that violated the order, even if the violator did not intend to violate the order, *see Robin Woods, Inc. v. Woods*, 28 F.3d 396, 399 (3d Cir. 1994) (where injunction prevented doll manufacturer from identifying designer was affiliated with company, finding that conduct, even though based on good faith advice of counsel “was not technical or inadvertent” because defendant “consciously chose to associate Mrs. Woods with dolls that Alexander would manufacture”); (2) where the violator knew that the conduct violated the order or took no steps to ensure compliance with

the order, *see Chao v. Koresko*, Nos. 04-3614, 05-1440, 05-1946, 05-2673, 2005 WL 2521886, *6 (3d Cir. Oct. 12, 2005) (finding that where party knew documents were responsive to subpoena and failed to produce them, failure to produce was “neither ‘technical’ nor ‘inadvertent’” despite sincere belief that documents were protected by privilege); *FTC v. Productive Mktg, Inc.*, 136 F. Supp. 2d 1096, 1110 (C.D. Cal. 2001) (where defendants were aware of existence of misdirected funds, failure to account for funds despite order’s requirement that all funds be accounted for constituted “a gross omission” and not “a harmless technical violation” of injunction); *Cobell v. Babbitt*, 37 F. Supp. 2d 6, 20–22 (D.D.C. 1999) (finding that violation was “substantial” where contemnor undertook no effort to comply with plain language of order and that contempt finding was proper); or (3) where the violations were “numerous” or “pervasive,” *see Halderman*, 154 F.R.D. at 608 (where violative conduct was, in part, “pervasive,” rejecting argument that violations were technical or inadvertent); *Pub. Interest Research Group*, 1988 WL 156725, *5 (rejecting argument that violations were technical and inadvertent and finding contempt in part because of the party’s “numerous” order violations).

35. Coercive and compensatory sanctions are proper remedies for civil contempt. *See United States v. United Mine Workers*, 330 U.S. 258, 303–04 (1947).

36. Compensatory sanctions are “payable to the complainant as compensation for damages caused by the contemnor’s noncompliance.” *Roe v. Operation Rescue*, 919 F.2d 857, 868 (3d Cir. 1990). Coercive sanctions are “payable to

the court, but defendant can avoid paying the contempt ‘fine’ by performing the act required by the court’s order.” *Id.*; *see also Lundy v. Yost*, 405 F. App’x 690, 695–96 (3d Cir. 2011) (upholding imprisonment of contemnor as a civil contempt remedy because purpose of imprisonment was to induce compliance with the court’s order).

37. A civil contempt award “must be an attempt to compensate plaintiff for the amount he is out-of-pocket or for what defendant by his wrong may be said to have diverted from the plaintiff or gained at plaintiff’s expense.” *See Nat’l Drying Mach. Co. v. Ackoff*, 245 F.2d 192, 194 (3d Cir. 1957); *see also McGregor v. Chierico*, 206 F.3d 1378, 1388–89 (11th Cir. 2000) (holding that consumers are entitled to full refunds where a “seller’s misrepresentations tainted the customer’s purchasing decision[]”); *cf. Ranco Indus. Prods. Corp. v. Dunlap*, 776 F.2d 1135, 1138–39 (3d Cir. 1985) (upholding finding of compensatory damages based on amount of sales lost due to contemnor’s conduct); *Vuitton et Fils S.A. v. Carousel Handbags*, 592 F.2d 126, 130 (2d Cir. 1979) (noting in a trademark matter that civil contempt sanctions are meant to “restore the parties to the position they would have held had the injunction been obeyed”).

38. The 2007 Order allows for FTC enforcement action to redress violations of the 2007 Order. *See* Dkt. No. 2, §§ VII, IX at 7–8, 9. As such, the government may seek compensatory relief for consumers in this matter. *See FTC v. Kuykendall*, 371 F.3d 745, 764 (10th Cir. 2004) (en banc) (holding that the FTC could “seek sanctions on behalf of injured consumers,” including consumers’ actual loss, after proving a violation of a permanent injunction); *see also FTC v. EDebitPay*, 695 F.3d 938, 945 (9th

Cir. 2012) (“We join our sister circuits today and hold that district courts have broad discretion to use consumer loss to calculate sanctions for civil contempt of an FTC consent order.”); *FTC v. Trudeau*, 579 F.3d 754, 771 (7th Cir. 2009) (“Consumer loss is a common measure for civil sanctions in contempt proceedings and direct FTC actions.”); *McGregor v. Chierico*, 206 F.3d 1378, 1388–89 (11th Cir. 2000) (in an FTC contempt action, affirming assessment of compensatory damages in the amount of gross sales).

39. Based on the findings of fact and conclusions of law, this Court holds Bayer in civil contempt of the 2007 Order.

40. To coerce Bayer’s compliance with the 2007 Order, which includes a requirement that Bayer recall all its advertising and packaging making unsubstantiated claims as found by this Court, Bayer is hereby ordered to pay an amount of \$25,000 to this Court for each day that Bayer continues to be in contempt of the 2007 Order.

41. The Court will set dates for discovery from Bayer concerning information the company has with respect to the amount of sales of PCH from launch of PCH to date, and briefing by both parties about appropriate remedies in addition to the coercive sanction above, including compensatory damages, for Bayer’s contempt.

Any foregoing conclusion of law that may be deemed a finding of fact is hereby incorporated into the findings of fact set forth above.

Dated: July 30, 2015

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